EXPLANATORY MEMORANDUM TO

THE ANIMAL HEALTH AND GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 No. 1229

1. Introduction

1.1 This Explanatory Memorandum has been prepared by Department for Environment, Food and Rural Affairs ("Defra") and is laid before Parliament by Command of Her Majesty.

1.2 This Explanatory Memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the Instrument

2.1 This instrument makes a number of technical changes to existing instruments and takes into account recent changes to EU legislation that were settled in the EU too late to be included in earlier EU Exit SIs. It also corrects minor errors in earlier EU Exit statutory instruments. It will ensure that retained EU law continues to operate effectively after the UK leaves the EU.

This instrument makes minor amendments to previously laid EU Exit instruments in the following subject areas:

- In Part 2, Transmissible Spongiform Encephalopathies ("TSEs") and Animal By-Products ("ABPs"); and
- In Part 3, Genetically Modified Organisms ("GMOs").

Explanations

What did any relevant EU law do before exit day?

2.2 **TSEs and ABPs**: the relevant five pieces of direct EU legislation below were first put in place as a result of the Bovine Spongiform Encephalopathy ("BSE") epidemic in the late 1980s and early 1990s. They have been updated frequently to reflect the development and decline of the epidemic. ABP legislation is relevant to TSE controls because scientific evidence has demonstrated that infectivity is concentrated in certain organs regulated by ABP legislation which are classified as Specified Risk Material ("SRM") which are destroyed to prevent their entry into the food chain. However, in addition, the legislation controls the use and disposal of ABPs to protect public and animal health against the spread of other diseases.

(i) **Regulation (EC) No. 999/2001** of the European Parliament and the Council lays down rules for the prevention, control and eradication of certain TSEs, including BSE in cattle and scrapie in sheep and goats. Related decisions subject to minor technical operability amendments are:

(a) **Commission Decision 2007/453** establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk; and

(b) **Commission Decision 2009/719** authorising certain Member States to revise their annual BSE monitoring programmes.

(ii) **Regulation (EC) No. 1069/2009** of the European Parliament and the Council lays down health rules as regards ABPs and derived products not intended for human consumption.

(iii) **Commission Regulation (EU) No. 142/2011** implements Regulation (EC) No. 1069/2009 of the European Parliament and the Council, which lays down health rules as regards ABPs and derived products not intended for human consumption.

2.3 **GMOs**: Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of GMOs sets out the procedures to follow, and the format for information to be submitted, prior to a GMO being released into the environment (cultivated or marketed). It provides a framework for the harmonised marketing of safe products produced from GMOs. Applications to import GMOs into, and trade within the EU are approved collectively by all EU Member States. This Directive provides discretionary provisions which allow Member States, or devolved governments within Member States, to decide against the cultivation of genetically modified crops in their territory. The process ensures that only safe GMOs are released. Any approval for the cultivation or marketing of a GMO is conditional upon it passing a science-based assessment of its potential impact on human health and the environment.

2.4 Council Decision 2002/813/EC specifies a standard format for summarising applications for consent for trials of GMOs.

2.5 Commission Decision 2003/701/EC specifies a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market.

Why is it being changed?

2.6 The amendments made by regulations 2, 3 and 4 of this instrument ensure that the law on TSEs and ABPs function correctly after the UK has left the EU by including the following recent amendments to EU law that were settled in the EU too late to be included in earlier EU Exit legislation.

- Commission Implementing Regulation (EU) 2019/1084 of 25 June 2019, amending Regulation (EU) No. 142/2011 as regards the harmonisation of the list of approved or registered establishments, plants and operators and the traceability of certain animal by-products and derived products.
- Commission Implementing Regulation (EU) 2019/1091 of 26 June 2019, amending Annex IV to Regulation (EC) No. 999/2001 of the European Parliament and of the Council as regards the requirements for export of products containing processed animal protein derived from ruminants and non-ruminants.
- Commission Implementing Regulation (EU) 2019/1177 of 10 July 2019 amending Regulation (EU) No 142/2011 as regards imports of gelatine, flavouring innards and rendered fats.

2.7 The EU Regulations listed above will only require minor changes to ensure they remain operable after EU Exit. These include references to a system in the UK to replace the Trade Control and Export System (TRACES) system operating in the EU.

2.8 Regarding GMOs, the amendments in regulation 5 of this instrument do not make changes to policy. They ensure that retained EU legislation continues to be interpreted

with certainty and to operate effectively. These issues were identified in the Fiftieth Report of the Joint Committee on Statutory Instruments in March 2019, and are relatively minor in nature. As a responsible Government we are acting to correct them using the first available suitable legislative vehicle.

2.9 The changes in regulation 5 of this instrument correct inconsistencies in the language used in S.I. 2019/90. In regulation 9 of S.I. 2019/90, which amended the Annex to Decision 2001/813/EC, the term "countries" was used when "constituent nations" would have been consistent; regulation 5(2) corrects that. In regulation 10 of S.I. 2019/90, which amended Commission Decision 2003/701/EC, the term "notification" was used when "consent" would have been consistent; regulation 5(3) of this instrument corrects that, and also revokes a short provision which should have been revoked by S.I. 2019/90. In each case, the reason for the amendment is in the interests of legal certainty.

What will it now do?

2.10 The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170) has been amended by Part 4 of the Animal Health, Invasive Alien Species, Plant Breeders' Rights and Seeds (Amendment etc.) (EU Exit) Regulations 2019 to ensure that retained direct EU legislation will continue to work after the UK has left the EU. Part 2 of this instrument includes operability amendments to Regulation (EC) No. 999/2001 and further amends S.I. 2019/170 to ensure that recent amendments to EU legislation are addressed.

2.11 The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90) amended retained EU law concerning controls over the deliberate release of GMOs into the environment, to ensure it continues to operate effectively after the UK leaves the EU.

2.12 The amendments made in regulation 5 of this instrument will correct minor errors in S.I. 2019/90, to ensure that EU law continues to operate effectively after the UK leaves the EU.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument corrects errors previously reported by the Joint Committee on Statutory Instruments in the Fiftieth Report of Session 2017-19, in regulations 9 and 10 of the Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90). In consequence, this instrument is being issued free of charge to recipients of S.I. 2019/90.

3.2 This instrument is made subject to the urgent 'made affirmative' procedure. The Ministerial statement in Part 2 of the Annex sets out the reasons for this decision.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.3 The powers under which this instrument is made cover the entire United Kingdom.

4. Extent and Territorial Application

4.1 The instrument extends to the United Kingdom and applies to England, Scotland, Wales and Northern Ireland.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble, has made the following statement regarding Human Rights:

"In my view the provisions of the Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument is made in exercise of powers conferred by the European Union (Withdrawal) Act 2018 which provides that a Minister of the Crown may by regulations make such provisions as the Minister considers appropriate to prevent, remedy or mitigate any failure of retained EU law to operate effectively or any other deficiency in retained EU law arising from the withdrawal of the UK from the EU.

7. Policy background

What is being done and why?

7.1 This instrument is being made to maintain the effectiveness and continuity of UK legislation and retained direct EU legislation that would otherwise be left partially unworkable following the withdrawal of the UK from the EU. It also addresses EU legislative changes which have recently been settled in the EU and makes corrections to earlier EU Exit SIs.

7.2 This instrument only makes amendments which are legally necessary to achieve its objectives following the withdrawal of the UK from the EU. It does not introduce any changes of policy for TSEs, ABPs or for GMOs and it will not produce any impact on businesses or the public.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8(1) of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the UK from the EU. This instrument is also being made under paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 (which includes the power to modify retained EU law and to make supplementary, incidental or consequential provision). In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 There are no plans for consolidation.

10. Consultation outcome

10.1 This instrument was not subject to formal consultation.

10.2 Defra has engaged with the Devolved Administrations, who have supported these proposed changes but has not carried out any engagement on this instrument with industry because it only makes amendments which are legally necessary to achieve its objectives following the withdrawal of the UK from the EU. It does not introduce any changes of policy for TSEs, ABPs or for GMOs and it will not produce any impact on businesses or the public.

11. Guidance

11.1 No guidance is required as the changes are minor and technical in nature.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because this instrument relates to the maintenance of existing regulatory standards.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 This instrument largely maintains the status quo, or corrects identified errors, and therefore does not introduce new duties or burdens on business.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is through the course of normal departmental business as no substantive changes to current practices are being introduced.

14.2 As this instrument is made under the European Union (Withdrawal Act) 2018 no review clause is required.

15. Contact

15.1 Katie Barnes at the Department for Environment, Food and Rural Affairs, telephone: 020 8026 3469, email: katie.barnes@defra.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Catherine Harrold, Deputy Director for Future Animal & Plant Health, Endemics and Traceability at the Department for Environment, Food and Rural Affairs, can confirm that this Explanatory Memorandum meets the required standard.

15.3 Lord Gardiner of Kimble, the Parliamentary Under Secretary of State for Rural Affairs and Biosecurity at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative instrument.	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees.
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	A statement that the instrument does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA 2018 SIs.	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence.	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the instrument is urgent.
Explanations where amending regulations under s.2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an instrument after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA 1972, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under s. 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an instrument after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 Lord Gardiner of Kimble, the Parliamentary Under Secretary of State for Rural Affairs and Biosecurity has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because in so far as the instrument uses the power in the European Union (Withdrawal) Act 2018, the instrument contains changes not affecting current standards and procedures.

2. Good reasons

2.1 Lord Gardiner of Kimble , the Parliamentary Under Secretary of State for Rural Affairs and Biosecurity has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These reasons are set out in section 7 in the main body of this Explanatory Memorandum.

3. Equalities

3.1 Lord Gardiner of Kimble, the Parliamentary Under Secretary of State for Rural Affairs and Biosecurity has made the following statement:

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts".

3.2 Lord Gardiner of Kimble, the Parliamentary Under Secretary of State for Rural Affairs and Biosecurity has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Lord Gardiner of Kimble, the Parliamentary Under Secretary of State for Rural Affairs and Biosecurity have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010".

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.

5. Urgency

5.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view by reason of urgency, it is necessary to make the Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019, without a draft of the instrument containing the regulations being laid before, and approved by a resolution of, each House of Parliament."

5.2 The Government has concluded that the 'made affirmative' procedure provided for in the European Union (Withdrawal) Act 2018 ensures that this instrument is in place for exit day.

5.3 The Government considers it important to urgently have this instrument in place so as to provide confidence and certainty to the public and business and to ensure the effective functioning of the statute book after exit.

5.4 This is because this instrument needs to be made and laid so that it is visible to the EU Commission on Legislation.gov.uk in October when a vote is taken in the EU's Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) Committee on 11th October regarding the UK's expedited request to be approved as a third country for the purpose of trade in animals and animal products with the European Union after Exit day.

5.5 Using this procedure still allows for parliamentary scrutiny and Parliament will need to approve its making for it to remain in force.